

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0535]

OMB  
13  
16  
Certifier: [Signature]

**Agency Information Collection Activities; Announcement of OMB Approval;  
Protection of Human Subjects; Recordkeeping Requirements for Institutional Review  
Boards (IRB's)**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

---

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Protection of Human Subjects; Recordkeeping Requirements for Institutional Review Boards (IRB's)" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

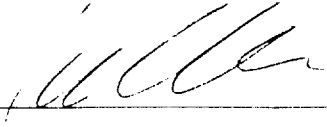
**FOR FURTHER INFORMATION CONTACT:** JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of August 4, 1998 (63 FR 41577), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays

a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0130. The approval expires on October 31, 2001.

Dated: November 5, 1998

November 5, 1998



William K. Hubbard  
Associate Commissioner for Policy Coordination

[FR Doc. 98-???? Filed ??-??-98; 8:45 am]

**BILLING CODE 4160-01-F**

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

